



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
67 Forest Street, Marlborough, MA 01752

MARYLOU
SUDDERS
Secretary
MONICA BHAREL
Commissioner

Tel: 617-624-6000

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

**MEMORANDUM
CLINICAL LABORATORY PROGRAM
NOTIFICATION OF CHANGES**

TO: Clinical Laboratories

FROM: Clinical Laboratory Program, Bureau of Health Care Safety and Quality

DATE: April 7, 2020

RE: Massachusetts Clinical Laboratory Program – Changes to Exempt Test List and Definition of Physician

This notice provides important information about changes to the state's Clinical Laboratory program and provides guidance to help providers comply with the state clinical laboratory requirements.

This notice supersedes the following circular letter: DHCQ 15-11-645, Addition of CLIA-Waived Blood Lead Testing to Exempt Test List.

I. Changes to Exempt Test List

Effective immediately, the state's Clinical Laboratory Program's Exempt Test List ("MA Exempt Test List") will include, but not be limited to, all tests on the then current list of tests granted waived status ("CLIA waived tests") under the Clinical Laboratory Improvement Amendments ("CLIA"). In addition to the CLIA waived tests, the MA Exempt Test List also includes:

- All tests on the CLIA list of tests categorized as provider-performed microscopy procedures ("PPMP"): and
- Throat Culture, screening only (including Bacitracin disk) and Urine Culture, screening only (growth or no growth).

Please keep in mind that the tests on the MA Exempt Test List may change.

II. Definition of “Physician”

Effective immediately, “physician” is defined as follows solely for the purposes of the clinical laboratory licensure program statutes and regulation:

“A “physician” is any of the following types of professionals licensed by the Commonwealth:

- Doctor of Medicine or Osteopathic Medicine;
- Doctor of Dental Medicine or Dental Surgery;
- Doctor of Podiatric Medicine;
- Doctor of Optometry; and
- Chiropractor.”

Please note that this notice is informational only and is not legal advice or a rule or regulation. The information in this notice is current as of the date of the notice and may be revised, updated, superseded, or replaced by information in future notices.

If you have any questions about the information in this notification, please contact the Clinical Laboratory Program at CLIALab@mass.gov.